IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

KD, a minor, by his parent and natural guardian, Kenneth Dieffenbach, and KENNETH DIEFFENBACH, in his own right	:	
Plaintiff,	:	Civil Action No. 07-515-***
v.	:	
UNITED STATES OF AMERICA,	:	
Defendant.	:	

UNITED STATES' OPENING BRIEF IN SUPPORT OF ITS MOTION TO DISMISS OR IN THE ALTERNATIVE, FOR SUMMARY JUDGMENT

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United States Attorney

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Dated: December 5, 2007

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NATURE AND STAGE OF THE PROCEEDING

This is a Federal Tort Claims Act ("FTCA") case in which the Plaintiffs allege medical malpractice by a federally employed health care provider at the National Institutes of Health ("NIH") in Bethesda, Maryland. An administrative claim was filed with NIH on behalf of the minor plaintiff only, and was denied. Plaintiffs subsequently filed suit in this court.

SUMMARY OF ARGUMENT

1. Under the Federal Tort Claims Act, 28 U.S.C. § 2671 *et seq*., a prerequisite for filing suit in District Court is that a plaintiff must first, within two years of the date the claim accrues, file an administrative claim with the appropriate federal agency. This plaintiffs failed to do, thus consideration of their allegations in this Court is barred.

2. The minor plaintiff's father failed to file an administrative claim in his own name, thus his claim, too, is barred.

STATEMENT OF FACTS

On December 13, 1995, physicians at the National Institutes of Health ("NIH") surgically implanted a pacemaker subcutaneously on the chest of the minor plaintiff, Kenneth Dieffenbach (KD), then age five. By May 29, 2002, seven years later, a physician at Children's Hospital in Boston, Massachusetts determined that the pacemaker's battery had reached the end of its useful life and turned it off. On September 7, 2003 KD had an episode of unconsciousness and on September 15, 2003, a week later, the pacemaker was surgically removed at Children's Hospital of Philadelphia and another device was implanted. The operation was performed without complications. KD was 13 years old at that time.

KD's father filed an administrative claim with NIH on behalf of KD, pursuant to the FTCA on March 28, 2006. That claim was denied on February 28, 2007, on Statute of Limitation grounds. The instant complaint was filed August 23, 2007.

The Complaint in the instant matter alleges a violation of the standard of care by the NIH health care providers who implanted the pacemaker in 1995, and negligence in connection with their follow up care, which had ended by early 2000. Specifically, the Complaint alleges that: NIH "fraudulently concealed" the fact that KD's pacemaker implantation was "part of an experiment") (Complaint paragraph 9, hereinafter "Comp. p.__"); NIH "intentionally misinterpret[ed] the minor plaintiff's medical records and based [treatment] recommendations on these misinterpretations (Comp. p.10); and NIH covered up the fact that it had experimented on KD and failed to inform his father that their treatment had been below the standard of care (Comp. p. 12, 13). Additionally, plaintiffs claim that the pacemaker itself was defective (Comp. p. 19), although they have not named the pacemaker manufacturer as a defendant.

ARGUMENT

I. Legal Standard

Pursuant to the Federal Rules of Civil Procedure, a party may move to dismiss a complaint for failure to state a claim on which relief can be granted. Fed.R.Civ.P. 12(b)(6). Where matters outside the pleadings are considered in deciding a motion to dismiss, the court will apply the same standard as when considering a motion for summary judgment under Rule 56. Thus, viewing the evidence and drawing inferences in the light most favorable to the non-moving party, the court will grant summary judgement to a defendant "where there are no genuine issue of any material fact, and the moving party is entitled to judgment as a matter of law." *Celotex Corp. v. Catrett*, 417 U.S. 317, 322 (1985); Fed.R.Civ.P.56(c); *accord In re IKON Office Solutions, Inc.*, 277 F.3d 658, 666 (3d Cir. 2002).

II. The Administrative Claim Was Untimely Filed

It is well settled that the Federal Tort Claims Act ("FTCA") is a limited waiver of sovereign immunity, which must be strictly construed. *United States v. Kubrick*, 444 U.S. 111, 119 (1979); 28 U.S.C. 2671 *et seq.* "A condition of that waiver is that suits be filed within the statutory time limitation." *Hughes v. United States*, 263 F.3d 272, 275 (3d Cir. 2001), citing 28 U.S.C. 2401(b). Thus, the FTCA's two-year statute of limitations applies. *Id.; accord Lehman v. Nakshian,* 453 U.S. 156, 161 (1981).

Pursuant to the FTCA, an administrative claim of negligence against the United States is forever barred unless it is presented to the appropriate federal agency "within two years of the claims's accrual". *Hughes,* 263 F.3d at 275. Federal law determines when a claim "accrues" for purposes of the FTCA. *Ciccarone v. United States*, 486 F.2d 253, 256 (3d Cir. 1973).

The Third Circuit has recognized that under the FTCA, "[d]etermining when the statute of limitations begins to run in a case is sometimes difficult, especially in cases claiming medical malpractice." *Hughes*, 263 F.3d at 273. The general rule is that "a tort claim accrues at the time of the plaintiff's injury." *Kubrick*, 444 U.S. at 119. *Kubrick* held that the "accrual" of a claim, for limitations purposes, does not occur when the plaintiff learns that *negligence* has been inflicted upon him, but instead, when he first knows the physical cause of a bad result, whether or not the cause was malpractice. *Id.* at 122. In other words, the claim accrues when the plaintiff knows the facts arguably showing causation of an injury. *Id.* *Kubrick* established an obligation on the part of the plaintiff, once he has "the critical facts that he has been hurt and who has inflicted the injury", to inquire of professionals who can tell him whether he has a good cause of action. *Id.* at 122. "There are others who can tell him if he has been wronged, and he need only ask.... Kubrick need only have made inquiry among doctors with average training and experience in such matters to have discovered that he probably had a good cause of action." *Id.* at 122-123. The court continued:

> A plaintiff such as Kubrick, armed with the facts about the harm done to him, can protect himself by seeking advice in the medical and legal community. To excuse him from promptly doing so by postponing the accrual of his claim would undermine the purpose of the limitations statute, which is to require the reasonably diligent presentation of tort claims against the Government.

Id. at 123.

The Third Circuit has applied this reasoning, finding that "[i]n a medical malpractice action under the FTCA, the statute of limitations is tolled until the putative plaintiff possesses facts which would enable 'a reasonable person to discover the alleged malpractice.'" *Hughes,*

263 F.3d at 275, quoting *Barren by Barren v. United States*, 839 F.2d 987, 991 (3d Cir. 1988), *cert. denied*, 488 U.S. 827 (1988).

On the other hand, the statute of limitations is not tolled just because a plaintiff is a minor. *See, e.g., McCall v. United States*, 310 F.3d 984, 988 (7th Cir. 2002) (collecting cases) ("we now join our sister circuits and hold that the FTCA's statute of limitations is not tolled during the period of a putative plaintiff's minority"). The reasoning behind these decisions is that the parents' knowledge is imputed to the minor child. *See, e.g. MacMillan v. United States*, 46 F.3d 377, 381 (5th Cir.1995) ("under the FTCA, the limitations period is not tolled during the minority of the putative plaintiff; rather 'his parent's knowledge of the injuries is imputed to him,'") *Zavala by Ruiz v. United States,* 876 F.2d 780, 783-84 (9th Cir. 1989)(the FTCA statute of limitations was not tolled because the parents had a duty to act on the child's behalf); *Clifford v. United States*, 738 F.2d 977, 980 (8th Cir. 1984). ("When a person is an infant, there are others legally responsible for his or her well-being. The parents or guardians would be under a duty to investigate the injury and its cause, and to take legal action within the time prescribed"); *Leonhard v. United States*, 633 F.2d 599, 624 (2d Cir. 1980)("[i]t is firmly established that the two-year [limitations] period is not tolled by the claimant's minority"); *cert denied*, 451 U.S. 908 (1981); *Robbins v. United States*, 624 F.2d 971, 972 (10th Cir. 1980) (same).

In this case, the cause of action arose either at the time KD's pacemaker was implanted on December 13, 1995, or - at the very latest - at the time KD's pacemaker was removed at Children's Hospital of Philadelphia on September 15, 2003. Any complications relating to the implantation would have been apparent at that time; no complications are noted in the medical records. See medical records, Bates numbered 492-493, attached as Exhibit 1. Any

complications relating to the device would have been apparent – at the very latest -- when the device was removed. None were reported. See Operative Note and Discharge Summary, attached as Exhibits 2 and 3. In short, Plaintiff can point to no injury caused by the pacemaker, much less any latent injury that appeared years later, which might arguably toll the statute of limitations.

Since KD's claim was not filed with NIH until March 28, 2006, more than ten years after the NIH implanted the pacemaker, more than six years after K.D. was last seen at NIH, and more than two years after the pacemaker was removed at Children's Hospital of Philadelphia , the Complaint filed in this court must be dismissed for failure to satisfy the administrative prerequisites of suit under the FTCA.

III. The Complaint Must be Dismissed as to The Adult Plaintiff, Kenneth Dieffenbach, For Failure to File an Administrative Claim.

The timely presentation of an administrative claim to the appropriate federal agency before filing suit applies to each plaintiff individually. As this court has previously noted in the FTCA context, "[i]f multiple claimants exist, each claimant must individually satisfy the jurisdictional prerequisite of filing a proper claim, unless another is legally entitled to assert such a claim on their behalf." *Frantz v. United States*, 791 F. Supp. 445, 447 (D. Del. 1992). Mere reference to the fact that there may be a related, derivative cause of action by a family member is "insufficient when it fails to provide the Government notice of the nature and amount of the claim." *Id.* at 448; *accord Dondero v. United States*, 775 F.Supp.144 (D. Del. 1991); *Jackson v. United States*, 730 F.2d 808 (D.C.Cir. 1984).

In this case, the administrative claim form (attached as Exhibit 4) named only the minor plaintiff, KD, as the claimant. K.D.'s father appears from the face of the claim only to be his minor son's representative, not to be a claimant in his own right. The form identifies no "sum certain" for the father's claim, as distinguished from KD's claim, and provides no indication that it was his intention to file two claims. To the contrary, counsel's cover letter accompanying the claim forms specifically identifies the father only as "the legal representative filing this claim on behalf of his minor son," and not as a claimant in his own right. See Exhibit 5. This failure to file administratively dooms his action in this court.

Accordingly, the Complaint must be dismissed for lack of jurisdiction to the extent that it presents claims by Mr. Dieffenbach in his own name.

CONCLUSION

For the reasons stated and upon the authorities cited herein, the United States respectfully requests the Court to dismiss the Complaint for failure to state a claim upon which relief can be granted.

Respectfully submitted,

COLM F. CONNOLLY
United States Attorney

By: /s/Patricia C. Hannigan
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MEDICAL RECORD | INPATIENT RECORD

Date Performed:	12-13-95
Preoperative Diagnosis:	Hypertrophic cardiomyopathy.
Primary Surgeon:	Lameh Fananapazir, M.D.
First Assistant Surgeon:	Dorothea R. McAreavey, M.D.
Other Assistant Surgeon(s):	None.
Operative Diagnosis:	Hypertrophic cardiomyopathy.
Title of Operation:	Implantation of dual chamber pacing system.
Specimens of Tissue Sent for Examination and Destination:	None.

DICTATOR IDENTIFICATION:

Name: Dorothea R. McAreavey, M.D.
Office Address: Bldg. 10 Rm. 7B15
Office Telephone: (301) 496-5817

DESCRIPTION OF OPERATION AND FINDINGS:

Procedure and Findings: This child was brought to the operating room in a fasted and sedated state. 600 mg of cefazolin was infused as antibiotic prophylaxis for the procedure. The left pectoral region was cleansed with multiple layers of betadine and draped in the usual sterile manner. Using 1% xylocaine, the left pectoral region was anesthetized. Using a Cook needle, two guide wires were introduced into the right side of the heart. A two centimeter incision was made into the left pectoral region. Using blunt dissection, deeper tissues were dissected and a pocket was fashioned in the pectoral fascia. Using an introducing system, pacing wires were introduced into the right side of the heart. The atrial pacing lead (Medtronic 4524) was positioned in the right auricular appendage. The P wave was 2.8 millivolts. There was loss of capture at 0.5 volts and pulse with 0.5 milliseconds. The resistance was 394 ohms. The ventricular lead (Medtronic 4024) was positioned at the apex of the right ventricle. The R wave was above the upper limit of detection, being more than 20 millivolts. There was loss of capture at 0.3 volts and pulse with 0.5 milliseconds. The resistance was 611 ohms. These leads were attached to deeper tissue with resorbable suture. They were also attached to a Pacesetter Trilogy pulse

generator, model 2350L. The generator was placed in the left pectoral pouch. The incision was closed with multiple layers of resorbable suture and with subcuticular stitch to skin. The procedure was uncomplicated, and subsequent checks of pacing function were satisfactory. The patient was returned to the recovery room in good hemodynamic state.

END OF REPORT

Date Performed: 12-13-95

INPATIENT OPERATION

Patient Identification
Dieffenbach, Kevin R. 29-18-76 6

Inpatient Record
NIH-999-2 (5-92)
P.A. 09-25-0099
File in Section 1: Summaries, Operations, History & Physical Exam

ACC#13761275/

CHILDREN'S HOSPITAL OF PHILADELPHIA
OPERATIVE NOTE

#886498

Name:	DIEFFENBACH, Kevin MR# ~~00886998~~
Date:	09/15/2003
Preoperative Diagnosis:	Hypertrophic Cardiomyopathy, Status-Post Dual-Chambered Pacemaker with Lead Dysfunction and Ventricular Tachycardia.
Postoperative Diagnosis:	Same.
Operation:	Removal of Pacemaker Generator, Removal of Transvenous Ventricular Pacing Leads, and Insertion of Transvenous AICD with Atrial Pacemaker.
Surgeon:	J. William Gaynor, M.D.
Assistant:	Dr. Rhodes and Dr. Rodriguez
Anesthesia:	General.
Complications:	

Clinical Note:

Kevin is a 12-year-old male with hypertrophic cardiomyopathy who had previously undergone dual-chambered pacemaker placement. The pacemaker is at end-of-life. Removal of the ventricular lead and insertion of the transvenous dual-chambered AICD is planned.

Procedure:

The patient was brought to the operating room and after adequate general anesthesia had been obtained, the chest was prepped and draped in a sterile fashion. The previous left infraclavicular incision was reopened and extended medially. The generator was removed and the leads were mobilized. The ventricular lead was then removed by Dr. Rhodes and a transvenous AICD lead inserted and secured with excellent pacing and sensing thresholds. The subcutaneous pocket was converted to a subpectoral pocket and the leads were secured to the chest wall. The atrial lead was tested and found to have excellent pacing and sensing thresholds. The leads were connected to the AICD generator, which was positioned in the pocket and secured to the chest wall with interrupted suture of 2-0 silk. The wound was irrigated with antibiotic saline solution, hemostasis was assured and ventricular fibrillation was induced and successfully and recognized and converted. The incision was repaired in layers. Dermabond and a sterile dressing were applied. Ventricular fibrillation was again induced and successfully recognized and converted. The chest x-ray was obtained which revealed no pneumothorax and good position of the leads. The patient was awakened, extubated and taken to the recovery room in stable condition.

J. William Gaynor, M.D.

JWG:rcf/TransRx/Diffenbach-Kevin-09-15-03-JWG
Date Dictated: 09/15/2003
Date Typed: 10/04/2003

THE CHILDREN'S HOSPITAL OF PHILADELPHIA

Discharge Summary ()
Patient Name: DIEFFENBACH, KEVIN
MRN: 00886498
BILLING NUMBER: 13761275
ATTENDING: LARRY RHODES, MD
Admitted: 09/08/2003

Discharged: 09/17/2003

ADMISSION DIAGNOSIS: Syncope.

DISCHARGE DIAGNOSIS: ICD placement.

REFERRING PHYSICIAN:
Dr. Jeffrey Heckert
3809 Highway 1
Rehoboth Beach, DE 19971

CIRCUMSTANCES SURROUNDING ADMISSION: The patient is a 13-year-old male with hypertrophic obstructive cardiomyopathy who presented after an episode of syncope. He was transferred from an outside hospital in Delaware after a syncopal episode. The patient was on the playground with his sister when he felt short of breath. He sat down while his mother went to call for help. By the time she returned, he had fallen to the ground. She described his whole face as turning blue and he was unresponsive. By the time the paramedics arrived, he was awake, alert and lucid back to his baseline. The patient did not describe any chest pain or palpitations prior to the event, no dizziness. He did have urine and stool incontinence. At the outside hospital, the patient's vital signs were stable. He had some isolated PVCs on telemetry and was transferred to CHOP CICU. In the CICU, he had no events on telemetry and was transferred to the general cardiology floor. Also in his HPI, the patient reports last week being ill with vomiting x 1, headache, chills and sore throat. He received a three day course of Zithromax and his symptoms improved.

PAST MEDICAL HISTORY: A history of a small VSD, history of hypertrophic obstructive cardiomyopathy diagnosed at age 5. He says he has been completely asymptomatic from this condition and is followed in Boston by cardiology. In 1995, he had a pacemaker placed as part of a NIH study protocol for hypertrophic obstructive cardiomyopathy. The pacemaker

currently, the battery was turned down and the patient and his family claim it no longer is working.

MEDICATIONS: Verapamil SR 180 mg once a day.

He has no known drug allergies.

FAMILY HISTORY: Noncontributory.

SOCIAL HISTORY: His parents are divorced and he lives with his mother in Delaware. He is an 8th grader. Shots are up-to-date.

On physical exam, his had no temperature, heart rate was 78, respiratory rate was 22, blood pressure was 120/61. He was satting 98% on room air. His weight was 58 kg. He was well-appearing in no acute distress. HEENT exam showed moist mucous membranes. His lungs were clear bilaterally. His heart was regular rate and rhythm, normal S1 and S2, 2/6 holosystolic murmur at the apex with radiation to the left sternal border. His belly was soft, nontender. His liver was at the right costal margin. Extremities warm and well-perfused and neurologic exam nonfocal.

LABS ON ADMISSION: A CBC from the outside hospital showed a white blood cell count of 7.7, hemoglobin 13.7, platelets 219. A basic metabolic showed a sodium of 139, potassium 3.7, chloride 102, BUN 17, creatinine 0.7, bicarb of 21, glucose 181, alk phos 177, total protein 7.1, albumin 4.2, bilirubin 0.3, ALT 34, AST 60, myoglobin was 92 and troponin was less than 0.2. He had an EKG which showed normal sinus rhythm, left atrial enlargement and biventricular hypertrophy. His chest x-ray showed cardiomegaly, lungs with slight increased vascular markings. An echo showed decent function, severe left atrial dilation, severe MR and asymmetric with ventricular hypertrophy.

The patient was transferred to the CICU under the suspicion that he had an episode of ventricular tachycardia or atrial fibrillation. He had no events on telemetry and was transferred to the cardiology floor. While he was on the general cardiology floor, he underwent further workup. He continued to have no significant events on telemetry with occasional PVCs and pauses of 1 to 1.5 second. He did, however, have pacer spikes from his old pacer. The cardiology attending was unable to interrogate the pacer due to the low battery. A representative of the company who made the pacer was also unable to interrogate the pacer. The pacer was thought to be a rogue pacer and needed to be removed. It was also determined that Kevin would benefit from a defibrillator

device to prevent any future syncopal or other episodes. He remained on verapamil during his stay. But since the pharmacy did not have the sustained release formulation, he received 80 mg q.8 hours. The patient, on an EKG, showed some suspicions for preexcitation. He went to the cath lab for further testing to see if he had any reentered circuits. He was determined to have no preexcitation circuits. The patient had an ICD placed on 9/15. His old ventricular lead was removed and the pacer was removed all together. He had a new ventricular lead placed and an A lead as well. The pacer was set to be a dual chamber defibrillator activated at a rate of 220 and would also pace at 40 beats per minute like a VVI pacer. The patient tolerated the procedure well. Once he had received 48 hours of Ancef and had adequate pain control, he was discharged to home.

The patient was discharged on 9/17. At the time of discharge, his vital signs were a temperature of 37.1, heart rate 100, respiratory rate 24, blood pressure 108/60. In general, he was well-appearing, no acute distress. HEENT exam: Normocephalic, atraumatic. Moist mucous membranes. Lungs were clear to auscultation bilaterally. Heart was regular rate and rhythm, normal S1 and S2, harsh 3/6 systolic murmur at the left sternal border, good peripheral pulses. His belly exam was soft, nontender and nondistended. Extremities: Warm and well-perfused. Neurologic: Nonfocal. Skin: He had a well-healed incision in his upper left chest.

MEDICATIONS: Verapamil SR 180 mg once a day, Ibuprofen 400 mg every six hours as needed, Tylenol 650 mg every four hours as needed, oxycodone 2.5 mg every six hours as needed.

His diet was p.o. ad lib. Activity as tolerated and he was told to follow-up with Dr. Rhodes in two weeks and told to call the doctor with any change in mental status, increased

respiratory rate, increased work of breathing, any fainting or near fainting episodes, any chest pain, palpitations or shortness of breath.

Dictated By: DEBORAH PALMER, MD

Attending Physician: LARRY RHODES, MD

DD: 10/04/2003
DT: 10/04/2003
TL127/JOB:2238241

Signed: LARRY RHODES, MD
10/23/2003 14:44 EDT

The Children's Hospital of Philadelphia

OR-101
Rev. 07/03

MR# 00881498
6229/CICU
MR# DIEFFENBACH, KEVIN
115 B FRANKLIN A 12 M1 PRO
LEWES, DE 19958 M
AGE DATE OF BIRTH 07/08/2003
04/13/1940 SOKOWSKI, SUSAN
ACCOUNT# 302-345-6374 ACC13761275
(PATIENT PLATE IMPRINT)

CONSENT TO OPERATION, DIAGNOSTIC PROCEDURE, MEDICAL TREATMENT AND BLOOD TRANSFUSION

Diagnosis: Hypertrophic Cardiomyopathy

1. I consent to Dr. Gaynor and whomever he/she may designate performing upon (Patient Name) Kevin Dieffenbach Age _____ the following operation, diagnostic procedure and/or medical treatment (state procedure(s)): Pacemaker Removal AICD placement

If any conditions are revealed in the course of the operation which, in the opinion of the doctor(s) authorized by this consent, require procedures in addition to or different from those now contemplated, I also authorize the performance of such procedures.

2. I have been informed of:
   (a) the nature of the proposed operation, procedure and/or treatment, including its potential benefits and the likelihood of success;
   (b) the alternatives -- including no operation, procedure and/or treatment.
   (c) the risks of, the possibilities of complications from, and the consequences of the proposed operation, procedure and/or treatment -- including those related to anesthesia and/or sedation and recuperation-- all in sufficient detail to permit me to make a reasonable decision in giving this consent. I also am aware that, in the practice of medicine, other unexpected risks or complications may occur. I further acknowledge that no guarantee or assurance has been made as to the results that may be obtained.
3. I understand that anesthesia involves risks in addition to those of the operation, procedure and/or treatment itself. These include, but are not limited to such things as injury to teeth or dental work, damage to vocal cords, respiratory problems, minor pain and discomfort, damage to arteries or veins, headaches, and nausea or vomiting. Severe adverse drug reactions, brain damage or death may also occur but are rare.
4. I understand that, if it is medically indicated to receive a transfusion of blood or blood products, the blood will be supplied by sources available to the Hospital and tested in accordance with federal regulations. I understand that there are risks to transfusion which include allergic, febrile (fever) and hemolytic (when transfused red blood cells are destroyed by antibodies in the circulation) transfusion reactions. Although the risk is extremely low, transmission of infectious disease such as hepatitis, AIDS (Acquired Immune Deficiency Syndrome), West Nile Virus, or HTLV-I/II (a virus associated with certain leukemias and nervous system disorder) is possible. I also understand that, as a result of ongoing efforts to improve the safety of the blood supply, in rare cases I may be contacted later with information that relates to the blood or blood products I received and that was not known at the time of the transfusion. I have been informed of the potential risks and alternatives, which include directed or autologous donations and I consent to blood transfusion or the transfusion of blood products if my doctor believes it is medically indicated.

I understand that this consent for transfusion of blood or blood products applies to (check option which applies)

_____ *today*

_____ *this hospitalization*

_____ *outpatient transfusions during the period of* ____/____/____ *to* ____/____/____. *(not to exceed one year from the date of consent).* (Month / Day / Year to Month / Day / Year)

✓ *the time during and for up to 7 days after the aforementioned operation or diagnostic procedure or treatment.*

5. I consent to the disposal of any tissue or parts which may be removed, including their use for teaching and research activities.
6. I consent to the medical procedures described above being performed at The Children's Hospital of Philadelphia (including its outpatient facilities), Children's Seashore House of The Children's Hospital of Philadelphia and/or the Hospital of the University of Pennsylvania.

Comments: Bleeding Infection

I certify that I have read and fully understand the above Consent and that all of my questions were answered to my satisfaction.

9/15/03 — Date
X AG — Signature of Consenting Party and Relationship to patient
Signature of Physician Obtaining Consent

IF CONSENTING PARTY IS NOT AVAILABLE TO SIGN THE ABOVE CONSENT:

Date | Time | Means of Obtaining Oral Consent | Consenting Party's Name and Relationship to Patient

Physician Obtaining Oral Consent | Witness

CLAIM FOR DAMAGE, INJURY, OR DEATH

INSTRUCTIONS: Please read carefully the instructions on the reverse side and supply information requested on both sides of this form. Use additional sheet(s) if necessary. See reverse side for additional instructions. 06-0219

FORM APPROVED
OMB NO.
1105-0008
EXPIRES 5-31-05

1. Submit To Appropriate Federal Agency:
Claims Office
OGC/GLD
Claims and Employment Law Branch
DHHS
330 Independence Ave., SW
Room 4760, Wilbur J. Cohen Federal Bldg.
Washington, D.C. 20201

2. Name, Address of claimant and claimant's personal representative, if any. (See instructions on reverse.) (Number, street, city, State and Zip Code)
Claimant: Kevin Dieffenbach (age 15 and SS#141-90-7338) Legal Representative: Kenneth Dieffenbach, Parent of Claimant
Address for both Claimant & Legal Representat
2 Pondview Lane, Lewes, DE 19958

3. TYPE OF EMPLOYMENT (MILITARY / CIVILIAN)	4. DATE OF BIRTH	5. MARITAL STATUS	6. DATE AND DAY OF ACCIDENT	7. TIME (A.M. OR P.M.)
	9/13/90	Single	5/9/2004	4:00 a.m.

8. Basis of Claim (State in detail the known facts and circumstances attending the damage, injury, or death, identifying persons and property involved, the place of occurrence and the cause thereof) (Use additional pages if necessary.)

The claimant was admitted to National Institute of Health on December 9, 1995 for the insertion of a pacemaker under the care of Dr. Fananapazir. Under the false pretense that a pacemaker was vital to protect his life, the claimant proceeded with the surgery. The pacemaker was later declared defective (1999) with no notice given to the claimant. The claimant suffered a heart attack on September 8, 2003. He is presently recovering from the last operation on May 9, 2004.

RECEIVED
CLAIMS OFFICE
HHS/OGC/GLD
2006 APR 26 PM 1:03

PROPERTY DAMAGE

9. NAME AND ADDRESS OF OWNER, IF OTHER THAN CLAIMANT (Number, street, city, State, and Zip Code)
N/A

BRIEFLY DESCRIBE THE PROPERTY, NATURE AND EXTENT OF DAMAGE AND THE LOCATION WHERE PROPERTY MAY BE INSPECTED. (See instructions on reverse side)
N/A

PERSONAL INJURY/WRONGFUL DEATH

10. STATE NATURE AND EXTENT OF EACH INJURY OR CAUSE OF DEATH, WHICH FORMS THE BASIS OF THE CLAIM. IF OTHER THAN CLAIMANT, STATE NAME OF INJURED PERSON OR DECEDENT

As a result of the implantation of the pacemaker, the claimant has suffered permanent heart and vessel damage. With additional operations, the claimant will suffer additional pain and suffering. Permanent scars on the chest is a major concern.

WITNESSES

11. NAME	ADDRESS (Number, street, city, State, and Zip Code)
1) Kenneth Dieffenbach	2 Pondview Lane, Lewes, DE 19958
2) Susan Sokowski	2 Pondview Lane, Lewes, DE 19958
3) Dr. Steven D. Colan	Children's Hospital of Boston

AMOUNT OF CLAIM (In dollars)

12. (See instructions on reverse) 12a. PROPERTY DAMAGE	12b. PERSONAL INJURY	12c. WRONGFUL DEATH	12d. TOTAL (Failure to specify may cause forfeiture of your rights.)
N/A	$5,000,000.00	N/A	$5,000,000.00

I CERTIFY THAT THE AMOUNT OF CLAIM COVERS ONLY DAMAGES AND INJURIES CAUSED BY THE ACCIDENT ABOVE AND AGREE TO ACCEPT SAID AMOUNT IN FULL SATISFACTION AND FINAL SETTLEMENT OF THIS CLAIM

13a. SIGNATURE OF CLAIMANT (See instructions on reverse side.)	13b. Phone number of signatory	14. DATE OF CLAIM
Kenneth Dieffenbach, Parent of Claimant	302-644-1467	3/24/06

CIVIL PENALTY FOR PRESENTING FRAUDULENT CLAIM
The claimant shall forfeit and pay to the United States the sum of not less than $5,000 and not more than $10,000, plus 3 times the amount of damages sustained by the United States. (See 31 U.S.C. 3729.)

CRIMINAL PENALTY FOR PRESENTING FRAUDULENT CLAIM OR MAKING FALSE STATEMENTS
Imprisonment for not more than five years and shall be subject to a fine of not less than $5,000 and not more than $10,000, plus 3 times the amount of damages sustained by the United States. (See 18 U.S.C.A. 287.)

95-108
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NSN 7540-00-634-4046

STANDARD FORM 95 (Rev. 7-85)
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April 25, 2006

Department of Health & Human Services
c/o Linda Vincent
Office of the General Counsel
Claims Office
330 Independence Avenue, SW
Room 4256
Wilbur J. Cohen Federal Building
Washington, DC 20201

Re: Kevin Dieffenbach

Dear Ms. Vincent :

In response to your letter dated April 12, 2006, I have provided the following documents for this claim and your consideration.

1. The amended Claim For Damage, Injury, or Death (SF-95)
2. A copy of the Lawyer-Client Representation Agreement for this claim

As you will see, Mr. Kenneth Dieffenbach, the custodial parent and father is the legal representative filing this claim on behalf of his minor son Kevin Dieffenbach. If you need any additional information, please contact me as soon as possible.

Sincerely,

Frederick K. Funk, Esquire

FKF/ejc